U.S. DEPARTMENT OF ENERGY
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT
OFFICE OF QUALITY ASSURANCE

AUDIT REPORT

OF

LOS ALAMOS NATIONAL LABORATORY

AT

LOS ALAMOS, NEW MEXICO

AUDIT NUMBER LANL-ARC-98-14

JUNE 22 THROUGH 26, 1998

Prepared by: _____ **Date:** _____
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Audit Team Leader
Office of Quality Assurance

Approved by: _____ **Date:** _____
Robert W. Clark
Acting Director
Office of Quality Assurance

1.0 EXECUTIVE SUMMARY

As a result of Quality Assurance (QA) Audit LANL-ARC-98-14, the audit team determined that the Los Alamos National Laboratory (LANL) is satisfactorily implementing the Office of Civilian Radioactive Waste Management (OCRWM) QA Program, with the exception of those areas where deficiencies exist, in accordance with the U.S. Department of Energy (DOE) OCRWM Quality Assurance Requirements and Description (QARD), DOE/RW-0333P, Revision 8, and LANL implementing procedures. QA Program Elements 1.0, 4.0, 5.0, 6.0, 7.0, 12.0, 16.0, 17.0, Supplements I, II, and Appendix C were determined to be satisfactory based on the activities evaluated during the audit. Element 2.0 was determined to be unsatisfactory due to deficiencies in both planning and document reviews. Supplement III was determined to be unsatisfactory due to additional deficiencies related to data traceability and technical reports not meeting procedure and program requirements. While unresolved project-wide Corrective Action Reports (CAR), VAMO-C-98-005, LVMO-C-98-006 and LVMO-98-C-002, globally impact QA Program Elements 4.0, 7.0, Supplements I and III, these areas, except for Supplement III, were determined to be satisfactory based on the current ongoing activities. There was no recent implementation for Element 15.0, and Supplement V was determined to not be applicable to LANL's current work activities.

The audit team identified four deficiencies during the audit that resulted in the issuance of three Deficiency Reports (DR), and one deficiency that was referred to an existing DR. These DRs are detailed in Section 5.5.1. In addition, one deficiency was corrected during the audit and is detailed in Section 5.5.2. One deficiency related to the inadequacy of the development of Technical Information Products (TIP) (technical reports) and the inconsistency in traceability of data in these reports. See DR LANL-98-D-108. Another deficiency addresses the lack of procedural process controls that require documented evidence of comments and documentation of how comments are resolved. See DR LANL-98-D-109. A third deficiency, DR LANL-98-D-110, identifies that QA records are not designated as required by AP-17.1Q (QA:L or QA:NA). A fourth deficiency was identified relative to the Civilian Radioactive Waste Management System Management and Operating Contractor (CRWMS M&O) staff signing Supplier Evaluation Reports (SER) in lieu of the Affected Organization (LANL) accepting the report. A DR was not issued since this is another example of a deficiency that was previously identified on DR OQA-98-D-003, the resolution of which will resolve this issue. An additional adverse condition relative to not documenting the receipt of calibrated measuring and test equipment (M&TE) when received was corrected during the course of the audit.

Additionally, there were four recommendations resulting from the audit, which are described in Section 6.0 of this report.

2.0 SCOPE

The audit was conducted to evaluate the LANL implementation of the OCRWM QA Program as described in the QARD and implementing procedures. Implementation, adequacy, and determination of effectiveness of LANL's implementation of the QA Program was assessed by the audit team through interview of cognizant personnel, reviews of documentation, evaluation of procedures and examination of facilities.

The following QA Program elements/requirements were evaluated during the audit, in accordance with the approved audit plan:

QA PROGRAM ELEMENTS

1.0	Organization
2.0	Quality Assurance Program
4.0	Procurement Document Control
5.0	Implementing Documents
6.0	Document Control
7.0	Control of Purchased Items and Services
12.0	Control of Measuring and Test Equipment
15.0	Nonconformances
16.0	Corrective Action
17.0	Quality Assurance Records
Supplement I	Software
Supplement II	Sample Control
Supplement III	Scientific Investigation
Supplement V	Control of the Electronic Management of Data
Appendix C	Mined Geologic Disposal System

The following QA Program elements were not evaluated, since LANL currently has no activities to which these elements apply:

3.0	Design Control
8.0	Identification and Control of Items
9.0	Control of Special Processes
10.0	Inspection
11.0	Test Control
13.0	Handling, Storage, and Shipping
14.0	Inspection, Test, and Operating Status
18.0	Audits
Supplement IV	Field Surveying
Appendix A	High-Level Waste Form Production
Appendix B	Storage and Transportation

3.0 AUDIT TEAM

The following is a list of audit team members and their assigned areas of responsibility:

Name/Title/Organization	QA Program Element
Kenneth O. Gilkerson, Audit Team Leader, OQA	12.0, 15.0, 16.0, Appendix C
Kristi A. Hodges, Auditor, OQA	2.0, 17.0, Supplement I, V
Emily S. Reiter, Auditor, OQA	1.0, 2.0, 5.0, 6.0
Edward P. Opelski, Auditor, OQA	4.0, 7.0, Supplements II, III

4.0 AUDIT MEETINGS AND PERSONNEL CONTACTED

The pre-audit meeting was held on June 22, 1998, at LANL offices in Los Alamos, New Mexico. Daily debriefing and coordination meetings were held with LANL management and staff, and daily audit team meetings were held to discuss audit status. The audit was concluded with a post-audit meeting on June 26, 1998, at LANL offices located in Los Alamos, New Mexico. Personnel contacted during the audit, including those who attended the pre-audit and post-audit meetings, are listed in Attachment I of this report.

5.0 SUMMARY OF AUDIT RESULTS

5.1 Program Effectiveness

The audit team concluded that, overall, LANL implementation of the QA Program is adequate and is being satisfactorily implemented for the scope of the audit. Weaknesses that are inherent to the project still exist in the areas of procurement, qualification of data and control of software, although the current activities in these areas were found to be satisfactory at the time of this audit. The results for each program element evaluated are contained in Attachment 2, Summary Table of Audit Results. In addition to the summary in Attachment 2, audit observations were noted and summarized as recommendations in Section 6.0

5.2 Stop Work or Immediate Corrective Actions Taken

There were no Stop Work Orders, immediate corrective actions, or related additional items resulting from this audit.

5.3 QA Program Audit Activities

The Summary Table of Audit Results is provided in Attachment 2. The audit checklists contain the details of the audit evaluation and the identification of the objective evidence reviewed. The checklists are kept and maintained as QA Records.

5.4 Technical Audit Activities

There were no technical areas evaluated during this audit.

5.5 Summary of Deficiencies

The audit team identified four deficiencies during the audit for which three DRs were issued and a referral to an existing DR (OQA-98-D-003). In addition, one deficiency was identified by the audit team and corrected prior to the post-audit meeting.

Synopses of deficiencies documented as DRs, the condition referenced to an existing DR, the condition corrected during the audit, and follow-up of previously issued CARs and DRs, are detailed below. The DRs have been transmitted under separate letters.

5.5.1 Deficiency Reports

DR LANL-98-D-108

The preparation of Technical Information Products (TIP) (i.e., Technical Reports) is inadequate. Applicability of the QA Program is not established in the TIP, nor is the traceability to TIP data established when previously submitted data was utilized. TIPs do not consistently identify applicable scientific notebooks (SN) in accordance with LANL-YMP-QP 3.23, Revision 4, *Preparation and Review of Technical Information Products and Study Plans*, (Attachment I). The procedure requirements for indicating "Draft" and including a statement in the TIP that no new data are presented are not implemented. In addition, the procedure does not meet the requirements of project procedure YAP 5.8Q, Revision 1, *Technical Document Preparation*, for technical document preparation.

DR LANL-98-D-109

The review processes for Requirements Traceability Matrices, TIPs, Study Plans, Quality Administrative Procedures, and Detailed Technical Procedures, do not establish processes that provide evidence of review comments and/or resolutions per QARD Section 2.2.10f. Records are not generated or retained that would demonstrate the process. Evidence of comments and their resolution are not provided as records.

DR LANL-98-D-110

LANL QA records packages did not contain QA indexing information on the first page of each record contained within a package, as required by

project procedure AP-17.1Q, Revision 0, *Record Source Responsibilities for Inclusionary Records.*

DR OQA-98-D-003

A deficient condition was identified by the audit team relative to CRWMS M&O staff signing Supplier Evaluation Reports in lieu of the Affected Organization (LANL) for accepting the report and the supplier. A DR was not issued, since this is another example of a deficiency that was previously identified and issued as DR OQA-98-D-003, the resolution of which should resolve this issue.

5.5.2 Deficiencies Corrected During the Audit

Deficiencies that are considered isolated in nature and only requiring remedial action can be corrected during the audit. The following deficiencies were identified and corrected during the audit:

LANL-YMP-QP-04.6, Revision 6, *Procurement,* Section 6.6, requires the completion of a Procurement Acceptance Report to document the results of an evaluation of the services received. A Procurement Acceptance Report had not been completed for calibration services associated with Purchase Request (PR) E 7591, which had been issued to Simco Electronics for the calibration of Measuring and Test Equipment (M&TE), on November 7, 1997. When interviewed, the Laboratory Technician indicated the reason he had not completed the Procurement Acceptance Report was that he had not understood requirements contained in the Statement of Technical and Quality Requirements for PR E 7591 forwarded to him through the OQA representative. The M&TE had not been used since received. The Laboratory Technician, with assistance from the OQA Representative, completed the Procurement Acceptance Report during the audit. This was viewed by the audit team as an isolated occurrence.

5.5.5 Follow-up of Previously Issued CARs and DRs:

VAMO- 98-C-005

It was noted during the audit that remedial actions have not been taken by LANL relative to this CAR due to a lack of direction by the CRWMS M&O. LANL still does not have a procedural method for passing technical and QA requirements to the Primary Standards Laboratory (PSL) at Sandia National Laboratories. LANL has suspended Yucca Mountain procurements from PSL. Although an Integrated Management Plan had been drafted by the CRWMS M&O for addressing remedial and corrective actions, LANL personnel had little input relative to the plan's potential for

impact on LANL's QA program. Furthermore, a review of this plan does not disclose how these specific remedial actions will be resolved. See related procurement issues in Recommendations, Section 6.0.

LVMO-98-C-006

As noted for VAMO-98-C-005, LANL has had little input into the commitments for resolving this project wide issue. However, some actions have been ongoing relative to getting software codes verified and validated, and coordinating activities with OQA and the CRWMS M&O. LANL does implement an acceptable, although cumbersome, software procedure.

LVMO-98-C-002

No actions have been taken by LANL relative to this CAR at the time of the audit.

LANL-97-D-003

Verification of corrective actions for this DR was ongoing during the audit by the OQA On-Site Laboratory Representative. A review of selected record packages was still necessary to close out this deficiency.

YM-97-D-107

This issue relative to "unqualified" data is still open pending actions to be completed by the CRWMS M&O and DOE Licensing, (i.e., initiating a Technical Assessment or Peer Review). Subsequent to these actions, LANL will update the records packages.

YM-97-D-075

The previous response relative to identifying cited references was rejected; however, a revised response was proposed to the QA Representative (QAR) that was determined to be acceptable and final resolution to this issue is in progress.

YM-98-D-022

The initial LANL response to this DR relative to the lack of SNs being used by the computer modelers was rejected due to an inadequate extent of condition evaluation. An amended response was being developed during the audit and discussions with the OQA QAR indicated that the response

would be acceptable. SNs have been generated as remedial action. This deficiency should be closed shortly.

LVMO-98-D-027

This DR issued to the CRWMS M&O has had project wide implications relative to the planning. New project procedures are in development to address this issue. Planning activities at LANL have been determined to reflect the same inadequacies that have been identified with the CRWMS M&O as well as other Affected Organizations.

6.0 Recommendations

1. It was observed during the audit that there is no central location or point of contact to determine the names and positions of staff augmentation (direct support services) subcontracted employees and the locations where they work. The same holds true for the names of the suppliers of analytical services and locations where analytical services are being or have been conducted. To make these determinations would require contacting each LANL Principal Investigator working on the Yucca Mountain Site Characterization Project (YMP). Implementation of the response to VAMO-98-C-005 may identify this information. However, it is recommended that this information be captured and maintained at a central location and/or with a point of contact as an on-going activity to determine if and when verification activities should occur.

2. Two consumable calibration standards were procured from Packard Instruments Incorporated, Meriden, Connecticut, through the University of California procurement process using PR 060BA. LANL-YMP-QP-04.6, Revision 6, *Procurement*, Section 6.0, states: "The purchase of consumable standards is controlled in accordance with QP-12.3." LANL-YMP-QP-12.3, Revision 4, *Control of Measuring and Test Equipment and Standards*, Section 6.1.1, states: "The Custodian documents the applicable information in accordance with QP-03.5." LANL-YMP-QP-03.5, *Documenting Scientific Investigations*, Section 6.1.5, states in part, "For work governed by a Los Alamos YMP detailed technical procedure (DP), the notebook will contain the following: Information required by ... Attachment 4 if ...standards are used." Although these procedures adequately describe the controls applied to consumable standards once they are received at LANL, none of these procedures describe the method used to procure consumable calibration standards. It was recommended that LANL-YMP-QP-04.6 be revised to indicate that the control of consumable standards instead of the purchase of them will be in accordance with QP-12.3. This change was initiated during the audit. Since the integrated response to VAMO-98-C-005 indicates the CRWMS M&O will take over procurement for the Affected Organizations, the method used to purchase consumable standards will be referred to VAMO-98-C-005 for resolution.

3. The Requirements Traceability Matrix (RTM) to Revision 7 of the QARD was being completed during the audit; however, Revision 8 of the QARD has been effective since June 1998. Discussions with responsible LANL personnel disclosed that, while a new RTM to Revision 8 has not been initiated, a review of the QARD changes suggest that the RTM to Revision 8 will be no different than Revision 7. Regardless, it is

recommended that this documentation be completed and submitted as soon as possible.

4. Based on recent issues relative to issuing reports containing unverified information from SNs, the following recommendation is made: A review of SNs should be performed before the generation/review/issuance of an associated milestone report. LANL performs an annual review, but it is likely that much of the data and information that supports the conclusions submitted in an interim or final report will not be validated by an independent technical reviewer (perhaps as much as a year's worth). The audit team views this as a weakness in the review process, but not a violation of a QARD or procedure requirement. Pertinent background information is to be available during the review, but no one seems to consider the report inputs; i.e., SNs and references, as applicable during the review process. Minimally, someone needs to examine the SNs before the work is published. In other words, it is more important to have the SN reviewed prior to generation/review/issuance of a deliverable than it is to have it looked at once a year. Real time reviews of SNs relative to the generation of reports and deliverables is recommended for management consideration.

7.0 List of Attachments

Attachment 1: Personnel Contacted During the Audit
Attachment 2: Summary Table of Audit Results

ATTACHMENT 1

Personnel Contacted During the Audit
Las Vegas

Name	Organization/Title	Pre-Audit Meeting	Contacted During Audit	Post-Audit Meeting
Bish, Dave	LANL Principal Investigator		X	
Burningham, A.	LANL Engineering Assurance, Las Vegas		X	
Clevenger, Mike	LANL Technical Assurance Project Lead	X	X	
Chipera, Steve	LANL, Laboratory Technician/M&TE		X	
Day, John	Contractor-Technical Assurance Liaison	X	X	
Gray, Elizabeth A.	LANL Training, DCC & QA records Coordinator	X	X	X
Harrington, Charles	LANL Project Leader Regulatory & Performance		X	
Hirons, Tom	LANL Laboratory Lead, Program Manager	X	X	X
Hersman, Larry	LANL, Principal Investigator		X	
Kaszuba, John	LANL Principal Investigator		X	
Martinez, Cloeves	LATA Technical Assurance	X	X	X
Runde, Wolfgang	LANL Principal Investigator		X	
Sanchez-Pope, A.	LATA Data Analyst		X	X
Serrano, Ramon	LANL Laboratory Standards Manager		X	
Sessions, Robert	LANL Software Configuration Manager	X	X	X
Snow, Margaret	LANL X-Ray Analyst Technician		X	
Strietelmeier, Betty	LANL Principal Investigator	X		
Souza, Larry	OQA Laboratory Representative	X	X	X
Stone, Dan	LATA Technical Data		X	X
Tait, C. Drew	LANL Principal Investigator	X		
Vandenplas, Bart	LATA Technical Specialist	X		
Vaniman, David	LANL Principal Investigator		X	
Young, Jim	LATA Technical Assurance	X	X	X

LANL Los Alamos National Laboratory
LATA Los Alamos Technical Associates
OQA Office of Quality Assurance

ATTACHMENT 2
AUDIT LANL-ARC-98-14
SUMMARY TABLE OF AUDIT RESULTS

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
1. 0	QP-01.4, Rev. 5	pp. 1-2			SAT	SAT	SAT
	QP-01.3, Rev. 5	p. 3			N/I	N/I	
2.0	QP-02.5, Rev. 4	pp. 5-7			SAT	SAT	UNSAT
	QP-02.7, Rev. 4	pp. 7-8			SAT	SAT	
	QP-02.11, Rev. 6	pp. 8-9			SAT	SAT	
	QP-02.12, Rev. 3	p. 4			NI	NI	
	QP-02.15, Rev. 3	p.. 4	LANL-98-D-109	#3	UNSAT	SAT	
	QARD 2.2.5/	pp. 9-10	LVMO-98-D-027 *		UNSAT	SAT	
	QARD 2.2.10	pp.13-15	LANL-98-D-109		UNSAT	SAT	
4.0	QP-04.6, Rev. 5	pp. 16-20	VAMO-98-C-005*	#1, #2	UNSAT	SAT	SAT
5.0	QP-06.2, Rev. 7	pp. 21-22	LANL-98-D-109		UNSAT	SAT	SAT
	QP-06.3, Rev. 5	pp. 21-22	LANL-98-D-109		UNSAT	SAT	
6.0	QP-06.1, Rev. 8	pp. 23-24			SAT	SAT	SAT
7.0	QP-04.6, Rev. 5	pp. 16-20	CDA#1		UNSAT	SAT	
	AP-7.4Q, Rev. 2	pp. 25-28	OQA-98-D-003*		SAT	UNSAT**	SAT
12.0	QP-12.3, Rev. 3	pp. 29-32			SAT	SAT	SAT
15.0	YAP-15.1Q,, Rev. 3	pp. 33-38			NI	NI	NI
16.0	AP-16.1Q, Rev. 2	p. 38			SAT	SAT	SAT
	AP-16.2Q, Rev. 2	p.38			SAT	SAT	
	AP-16.3Q, Rev. 1	p.38			SAT	SAT	
17.0	AP-17.1Q, Rev. 0	pp. 39-42	LANL-98-D-110		SAT	UNSAT	SAT
SI	QP-03.21, Rev. 7	pp. 42-46	LVMO-98-C-006*		UNSAT	SAT	SAT
	QP-3.20, Rev. 5	pp. 46-49	LVMO-98-C-006*		UNSAT	SAT	

QA ELEMENT/ ACTIVITIES	DOCUMENT REVIEW	CHECKLIST PAGES	DEFICIENCIES	RECOMMENDATIONS	PROGRAM ADEQUACY	PROCEDURE COMPLIANCE	OVERALL
SII	QP-08.1, Rev. 6	pp. 50-54			SAT	SAT	SAT
	YAP-SII.1Q, Rev. 1, ICN 1	pp. 50-54			SAT	SAT	
	YAP-SII.2Q, Rev. 2	p. 54			SAT	SAT	
	YAP-SII.4Q, Rev. 0	p. 54			SAT	SAT	
SIII	QP-03.5, Rev. 8	pp. 54-59		#4	SAT	SAT	UNSAT
	QP-3.23, Rev. 4	pp. 59, 11-15	LANL-98-D-108 LANL-98-D-109	#4	UNSAT	UNSAT	
	QP-3.25, Rev. 3	p. 60			NI	NI	
	QP-08.3, Rev. 6	pp. 60-63	YM-97-D-107* LVMO-98-C-002*		UNSAT	SAT	
SV	QARD	p.64			NI	NI	NI
TOTAL	**PAGES = 64**		3 New DRs 1 CDA	4	**SATISFACTORY**		

LEGEND:

CDA	Corrected During Audit
NI	Not Implemented
SAT	Satisfactory
UNSAT	Unsatisfactory

NOTE:
Deficiencies with an * denote that this document was issued prior to this audit, but the deficient condition still applies.
UNSAT with ** indicates that the deficient condition was not against LANL, but impacts its program